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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,328

04/13/2004

Mark A. Roehrig

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04/29/2008

3M INNOVATIVE PROPERTIES COMPANY

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

04/29/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/823,328	ROEHRIG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/01/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Summary**

1. Receipt of IDS filed on 02/18/08 is acknowledged.

### ***Restriction/Election***

Applicant's election without traverse of Group 1 claims 1-4 and 10-14 in the reply filed on 02/18/08 is acknowledged.

Claims 5-9 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/18/08.

Accordingly, claims **1-4 and 10-14** are under prosecution.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "releasably stored dosage". It is not clear what the applicant intends to mean by releasably. Claim 1 recites the limitation "substantially". The term substantially in claim 1 is a relative term which renders the claim indefinite. The term substantially is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 11 recites the limitation "less than about". The term less than encompasses any value which is less than the defined value and about is an approximation. The claim is therefore indefinite. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilgard et al.(US PG pub. 20050019383).

Pilgard et al. teaches patches for dermal and transdermal drug delivery (abstract). The reference teaches barrier layer separating the active ingredient from the adhesive. The barrier layer may be in the form of a polymer or a metal layer impermeable to the active ingredient and to the adhesive layer (see page 1, paragraph

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[0004]). The article has adhesive layer which adheres to skin, which has a first component constituting a continuous layer and at least a second component which is located in indentations in the adhesive surface of the first component and the second component is separated by barrier layer (see paragraph [0016], page 1). The second component may act as reservoir. (see paragraph [0022]). The barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way (see paragraph [0048] on page 3). The barrier layer comprises a metal foil which could be aluminum or a laminate of one or more layers or plurality of barrier layers (see paragraphs [0025, 0026, 0028 and 0048] on pages 2 and 3. The article comprises a backing layer which may be polyurethane film or foam or combination of film layers (see paragraph [0051]), (instant specification exemplifies polyurethane as one of the components constituting the backing layer, see page 8 second paragraph). Since the chemical compound comprising the backing layer in prior art is similar to what is claimed as backing layer, the physical characteristic of the backing layer being translucent is inherent. The flange which is a continuation of barrier layer is taught to be of an average thickness of less than about 0.045mm (see page 1, paragraph [0016]). Therefore, regarding the claimed size of the barrier layer, it is the position of the examiner that optimization of such parameter would have been within the purview of a skilled artisan absent evidence of any unexpected results associated with the claimed size.

Furthermore, it would have been obvious to one of ordinary skilled in the art to modify the application of barrier layer and make it substantially continuous since the

prior art teaches that the barrier layer may be arranged in a pattern over the dressing in order to distribute the active ingredient in a desired way and come to the claimed invention with a reasonable expectation of success. based on the teachings of the prior art , it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to prepare a transdermal drug delivery device comprising reservoir, a barrier layer and backing layer with a reasonable expectation of success.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call  
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612